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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,773	11/28/2001	Yoshinobu Hanyu	P21651	9572

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RESTON, VA 20191

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,773

Applicant(s)

HANYU ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-15 and 17-24 is/are rejected.
- 7) ☒ Claim(s) 18-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 9/26/2004 to the Office action has been entered. Claims 1-3, 5-15 and 17-24 are pending.

1. The rejection of claims 1-24 under 35 U.S.C. 112, second paragraph is withdrawn.
2. The rejection of claims 9 and 21 under 35 U.S.C. 112, second paragraph is withdrawn.
3. The rejection of claims 1, 3, 5-6, 8, 1013, 15, 17, 20, 23 and 24 under 35 U.S.C. 102(b) as being anticipated by Samaritani (WO 95/35116, issued December 28, 1995) is withdrawn.
4. The rejection of claims 1, 7, 13 and 19 under 35 U.S.C. 102(b) as being anticipated by Bjorn et al. (WO 97/39768, issued October 30, 1997) is withdrawn.
5. The rejection of claim 18 under 35 U.S.C. 103(a) over Samaritani (WO 95/35116, issued December 28, 1995) in view of Morita et al. (6,156,343, issued December 5, 2000) is withdrawn.
6. The rejection of claims 2, 4, 14 and 16 under 35 U.S.C. 103(a) over Samaritani (WO 95/35116, issued December 28, 1995) in view of Bjorn et al. (WO 97/39768, issued October 30, 1997) is withdrawn.

NEW GROUNDS OF REJECTIONS

Claim Objections

7. Claims 1-3 and 4-12 are objected to because of the following informalities: the word "hydrogenated" in claim 1 and "polyysorbate" in claim 19, and phrase "one of" in claim 7 might be typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 1-3 and 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-3 and 4-12 are vague and indefinite because the preamble is for preparing a powder containing the physiologically active peptide, but there is no an active step for preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiological active peptide. Clarification is required.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 1-3, 5, 8-15, 17, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrand et al. (6103,697, issued August 15, 2000) further in view of Oyama et al. (6,117,434, issued September 12, 2000).

Bergstrand et al. disclose the preparation of pharmaceutical preparation containing a peptide (See column 12, lines 56-57). The active peptide may be admixed with mannitol, or cellulose derivatives or polyvinylpyrrolidone (See column 12, lines 56-67) and surfactants lecithin (see column 13, lines 53-55). A solution containing active peptide was dried by lyophilization (See example 34, column 9, lines 58-60). The physiologically active peptide is human growth hormone (See column 2, lines 15-20). The size of a particle is suitable for inhalation (mass median diameter less than 4 μm) (See column 13, lines 41-43).

Bergstrand et al. do not disclose the amount of a nonionic surfactant, a nonionic, organic, water-soluble binder and mannitol used in the method.

However, it would have been prima facie obvious to select the specific ratio of weight of these compounds used in the method for preparing a powder for containing a physiological active peptide, because the selection of the amount of these compounds used in the method represents routine optimization with regard to sequence, length and the amount of the compounds used in the method for preparing a powder containing a physiological active peptide.

Routine optimization is not considered inventive and no evidence has been presented that the weight ratio used in the method for preparing a powder containing a physiological active peptide was other than routine, that the method resulting from the optimization have any unexpected results or the results should be considered unexpected as compared to the closest prior art.

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Bergstrand et al. also do not disclose using hydrogenated lecithin.

Oyama et al. disclose using hydrogenated lecithin in a moisturizing composition in view of oxidation stability (See column 2, lines 32-33).

One of ordinary skill in the art at time of the invention would have been motivated to add hydrogenated lecithin in an aqueous solution containing active peptide because of the oxidation stability of hydrogenated lecithin as taught by Oyama et al. It would have been prima facie obvious to use hydrogenated lecithin in an aqueous solution containing active peptide in a process of preparing a powder.

Allowable Subject Matter

12. Claims 6-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 18-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 6-7, 18 and 19, no prior art has been found teaching or suggesting applying the water-soluble, nonionic cellulose derivative selected from the group of hydroxypropylcellulose, hydroxyethylcellulose and hydroxypropylmethylcellulose or the nonionic surfactant selected from the group of polysorbate, polyoxyethylenehydrogenated castor oil and a poloxamer to an aqueous liquid in a process of preparing a powder containing the physiologically active peptide.

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14. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung *J. Tung*
December 7, 2004

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

12/7/04